2018 Current Fiscal Year Report: Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

Report Run Date: 06/05/2019 10:25:32 AM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests	2529

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	04/26/2019	04/26/2021	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	No	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
Section 1834A(f)(1) of the Social Security Act (the Act) (42 USC 1395m-1)	07/01/2015	Continuing	No

15. Description of Committee Regulatory Negotiations Committee

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
To make recommendations to the Secretary and the Administrator regarding the basis of payment for new and reconsidered laboratory codes discussed during the 2018 Annual Laboratory Public Meeting. In addition, new Panel members were announced.	07/16/2018	07/17/2018

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$70,308.96	$71,022.26
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$7,116.87	$40,000.00

18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$24,120.23	$48,000.00
18d. Total	$101,546.06	$159,022.26
19. Federal Staff Support Years (FTE)	0.50	0.50

20a. How does the Committee accomplish its purpose?

The Panel may advise the Secretary of the Department of Health and Human Services (HHS), and the Administrator of the Centers for Medicare & Medicaid Services (CMS), on the following: 1)the establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and2)the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.In addition, the Panel may provide recommendations to the Secretary of HHS and the Administrator of CMS under section 1834A of the Act.

20b. How does the Committee balance its membership?

The Panel shall consist of up to 15 individuals with expertise in issues related to clinical diagnostic laboratory tests, which may include representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in clinical laboratory science or health economics, with regard to issues related to the development, validation, performance, safety, and application of such tests. Members shall be appointed by the Secretary, or CMS Administrator, or CMS Administrator’s designee.

20c. How frequent and relevant are the Committee Meetings?

Estimated Number of Meetings per Year - 4. The Panel is relevant because it considers and advises on the following issues:•Calculation of weighted medians of private payor rates for laboratory tests.•Phase-in of reductions in Medicare payment rates based on private payor rates, as required.•Application of market rates to establishment of Medicare payment rates.•Evaluation and designation of tests as advanced diagnostic laboratory tests as defined in section 1834A of the Act.•Whether to use crosswalking or gapfilling to determine payment for a specific new test.•The factors used in determining coverage or payment processes for new clinical diagnostic laboratory tests.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) is

required by law under section 1834A(f)(1) of the Social Security Act (42 U.S.C. 1395m-1) (the Act), as established by section 216 of Public Law 113-93, enacted April 1, 2014.

20e. Why is it necessary to close and/or partially closed committee meetings?

Not Applicable

21. Remarks

Designated Federal Officer

Glenn Charles McGuirk DFO

Committee Members	Start	End	Occupation	Member Designation
Baird, Geoffrey	07/01/2015	07/31/2018	Anatomic, Clinical, and Molecular Pathology	Representative Member
Baselski, Vickie	07/01/2015	07/31/2018	Microbiology	Representative Member
Bossler, Aaron	07/01/2018	07/31/2021	Medicine; Clincial Pathology; Moelcular Genetic Pathology	Representative Member
Chandra, Pranil	07/01/2018	07/31/2021	Chief Medical Officer;Molecular Genetic Pathology; Hematopathology	Representative Member
Clarke, William	07/01/2015	07/31/2018	Pathology/Toxicology Research	Representative Member
Hamilton, Stanley	07/01/2015	07/31/2018	Molecular Pathology	Representative Member
Hanson, Kimberly	07/01/2018	07/31/2021	Infectious Diseases	Representative Member
Kucherlapati, Raju	07/01/2015	07/31/2018	Genetics	Representative Member
Loy, Bryan	07/01/2015	07/31/2018	Laboratory Management	Representative Member
Marcus, Gail	07/01/2015	07/31/2018	Healthcare Business	Representative Member
Morrison, Carl	07/01/2015	07/31/2018	Molecular Pathology	Representative Member
Nakano, Karen	02/22/2017	02/22/2020	Centers for Medicare and Medicaid Services	Regular Government Employee (RGE) Member
Schoonmaker, Michele	07/01/2015	07/31/2018	Genetics	Representative Member
Sutphen, Rebecca	07/01/2015	07/31/2018	Molecular Genetics	Representative Member

Number of Committee Members Listed: 14

Narrative Description

The Panel may advise the Secretary of the Department of Health and Human Services (HHS), and the Administrator of the Centers for Medicare & Medicaid Services (CMS), on the following: 1)the establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and 2)the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	☐
Trust in government	☐

Major policy changes	☐
Advance in scientific research	☐
Effective grant making	☐
Improved service delivery	☐
Increased customer satisfaction	☐
Implementation of laws or regulatory requirements	☐
Other	☐

Outcome Comments

Not Applicable

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

Not Applicable

What is the approximate Number of recommendations produced by this committee for the life of the committee?

307

Number of Recommendations Comments

Approximately 209 recommendations (45 rec in 2015 + 45 rec in 2016 + 117 rec in 2017+ 102 rec in 2018) were generated for the life of the committee.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

85%

% of Recommendations Fully Implemented Comments

Approximately 85 percent of the CDLT Panel recommendations are fully implemented by the Agency.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments
Of the 15 percent that are not fully implemented, approximately 10 percent are partially implemented. For the remaining 5 percent, CMS may not be able to address these issues due to statutory constraints, or they may be addressed in future years as we are able to do so.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
Panel recommendations are verified and publically announced before they are made final and prior to posting on the CMS website.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☐
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☐

Action Comments
Not Applicable

Is the Committee engaged in the review of applications for grants?
No

Grant Review Comments
Not Applicable

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

Not Applicable